

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

KOHL, et al.

Conf. No. 2320

U.S. Pat. No. 7,470,791

Examiner: DAVIS, Z.N.

Issued: December 30, 2008

Art Unit: 1625

Title: **NOVEL PROCESS FOR THE PREPARATION OF ROFLUMILAST**

**REPLY TO DISMISSAL OF REQUEST FOR RECALCULATION OF PATENT TERM
ADJUSTMENT IN VIEW OF *WYETH***

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This is in response to the Dismissal rendered by the USPTO on the Decision on Request for Recalculation of Patent Term Adjustment In View of *Wyeth* having a mailing date of April 20, 2010. The one-month period for response set forth in the Decision expires May 20, 2010. Accordingly, this Response is timely filed.

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Conclusion begins on page 5 of this paper.

REMARKS

This Reply is being filed in response to the Dismissal rendered by the USPTO on the Decision on Request for Recalculation of Patent Term Adjustment In View of *Wyeth* having a mailing date of April 20, 2010. The Patent Owner had filed a Request for Recalculation of Patent Term Adjustment (PTA) In View of *Wyeth* for U.S. Patent No. 7,470,791 (hereinafter “the ‘791 Patent”) on March 25, 2010 under the Interim Procedures signed by Under Secretary Kappos on January 26, 2010 and published in the Federal Register (Vol. 75, No. 20) on February 1, 2010. The Decision states that the Request for Recalculation was dismissed for one or more reasons enumerated in reasons (A) through (G). The Patent Owner herein replies to the Decision.

Decision to Dismiss Request Is Improper

In determining PTA, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the PTO under 35 U.S.C. § 154(b)(1), as limited by any overlapping periods of delay by the PTO as specified under 35 U.S.C. § 154(b)(2)(A), any disclaimer of patent term by applicant under 35 U.S.C. § 154(b)(2)(B), and any delay attributable to the applicant under 35 U.S.C. § 154(b)(2)(C).

The PTA for the ‘791 Patent as determined by the Director under 35 U.S.C. § 154(b) and indicated on the face of the ‘791 Patent is 589 days. The PTA determination of 589 days is in error because the PTO failed to account for two separate PTO delays. In particular, the PTO failed to properly account for the PTO delay that occurred after the date that was three years after the filing date of the ‘791 Patent, pursuant to U.S.C. § 154(b)(1)(B). The correctly calculated PTA for the ‘791 Patent is 835 days.

The correct calculated PTA for the '791 Patent under 35 U.S.C. §§ 154(b)(1) and 154(b)(2) is the sum of the A Delay period and the B Delay period (*i.e.*, 589 days + 256 days), reduced by the sum of the number of days of overlap between the A Delay Period and the B Delay Period (10 days) and the period of applicant delay (*i.e.*, 0 days). Accordingly, the correct calculated PTA is 835 days.

The Director erred in the determination of PTA by treating the entire period of PTO examination delay under the A Delay period as a period of overlap between the A Delay period and the B Delay period, rather than correctly treating only that part of the A Delay period that occurred after the date that was three years after the actual filing date of the '791 Patent as overlap. Therefore, the Director erroneously determined that the net PTA was 589 days.

In *Wyeth v. Dudas*, 580 Supp. 2d 138 (D.D.C. 2008), the District Court for the District of Columbia explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining PTA. The Court of Appeals for the Federal Circuit affirmed the District Court's judgment (No. 2009-1120 (Fed. Cir., Jan. 7, 2010)). In accordance with *Wyeth*, the calculated PTA for the '791 Patent is properly determined to be 835 days as explained above (*i.e.*, (589 days + 256 days) minus (10 days)).

In order to qualify for recalculation under the Interim Procedure set forth by the USPTO, a form requesting a recalculation of the PTA must be submitted no later than 180 days after the patent has issued and the patent must be issued prior to March 2, 2010. In addition, this procedure is only available for alleged errors that are specifically identified in *Wyeth*.

The Patent Owner acknowledges that the '791 Patent issued more than 180 days prior to the filing of the Request for Recalculation on March 25, 2010. More specifically, the '791 Patent issued on December 30, 2008. The '791 Patent had issued prior to March 2, 2010 and was subject to the errors identified in the *Wyeth* decision, meeting the other criteria for recalculation. The *Wyeth* decision along with the Interim Procedures set forth by the USPTO on February 1, 2010 left the Patent Owner with a right to seek corrected PTA but without a remedy for obtaining that correction of PTA. While the USPTO acknowledged they had incorrectly calculated Patent Term Adjustment (PTA), the USPTO did not provide a remedy for those patent owners who fell outside the 180 day window, arbitrarily set by the USPTO, but were harmed by the incorrect calculation of PTA by the Director. The Patent Owner of the '791 Patent is one such owner.

Accordingly, the Decision to Dismiss the Request for Recalculation of Patent Term Adjustment In View of *Wyeth* was improperly dismissed because the Director incorrectly calculated the PTA at the time the '791 Patent issued.

The Patent Owner herein requests that the USPTO reconsider the Request for Recalculation of Patent Term Adjustment filed on March 25, 2010 and grant a corrected PTA of 835 days for the '791 Patent.

CONCLUSION

Based upon the above remarks submitted herewith, the PTA for the '791 Patent is believed to be correctly calculated to be 835 days. The Director is therefore respectfully requested to reconsider the Request for Recalculation of Patent Term Adjustment In View of *Wyeth* filed March 25, 2010 and issued a corrected Patent Term Adjustment. Favorable consideration is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments. In the event this paper is not timely filed, Patent Owner petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
THE NATH LAW GROUP

Date: May 20, 2010
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